



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JUL 16 1999

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The Honorable Charles E. Grassley  
United States Senate  
Washington, D.C. 20510-1501

Dear Senator Grassley:

Thank you for your letter of June 8, 1999, on behalf of several of your constituents, concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients . . . ." FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation (21 CFR 179), are enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR has been extended to July 19, 1999.

We have forwarded your constituents' correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of irradiated foods will take into account all of the data and information received.

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Because your constituents may be concerned about irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this responds to your concerns. If we may be of further assistance, please contact us again.

Sincerely,

*Jane F. Kirby*  
for Melinda K. Plaisier  
Interim Associate Commissioner  
for Legislation

Enclosures

cc: Dockets Management Branch  
(98N-1038)